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Aortic Annulus Stabilization Technique for Rapid Deployment Aortic Valve Replacement

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Abstract: Rapid deployment aortic valve replacement (RDAVR) with the use of rapid deployment valve systems represents a smart alternative to the use of standard aortic bioprosthesis for aortic valve replacement. Nevertheless, its use is still debatable in patients with pure aortic valve regurgitation or true bicuspid aortic valve because of the risk of postoperative paravalvular leak. To address this issue, an optimal annulus-valve size match seems to be the ideal surgical strategy. This article describes a new technique developed to stabilize the aortic annulus and prevent paravalvular leak after RDAVR. To confirm the feasibility, this technique was performed in six patients with severe symptomatic aortic stenosis who were scheduled to undergo aortic valve replacement at our center. All patients survived surgery and were discharged from the hospital. There were no new intracardiac conduction system disturbances observed, and a permanent pacemaker implantation was not required in any of the patients. The intraoperative and postoperative echocardiogram confirmed successful positioning of the valve, and no paravalvular leak was observed. In this preliminary experience, RDAVR through a full sternotomy or an upper hemisternotomy approach with the use of aortic annulus stabilization technique was safe, and no leak was observed. Future studies on large series of patients are necessary to confirm the safety and effectiveness of this technique in preventing paravalvular leak in patients with true bicuspid aortic valves or pure aortic regurgitation.

Key Words: Aortic valve replacement, Minimally invasive cardiac surgery, Rapid deployment aortic valve.

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The EDWARDS INTUITY and the new-generation EDWARDS INTUITY Elite Valve Systems (Edwards Lifesciences, Inc, Irvine, CA USA) are rapid deployment aortic bioprosthesis that couple the excellent hemodynamic characteristics of the well-known Perimount biological prosthesis (Edwards Lifesciences, Inc, Irvine, CA USA) with the advantage of a fast implanting system composed by a short stent placed below the annulus and three polypropylene U-fashion stitches placed at the nadirs of the three cusps (Fig. 1A). This new design has been developed and tested during the last few years, with very good hemodynamic and safety outcomes.[1–4] Nevertheless, in some particular conditions, such as a true bicuspid aortic valve or a pure aortic regurgitation, there may be a risk of mild-to-moderate paravalvular leak (PVL) after the valve placement that is mainly related to the intrinsic characteristics of the annulus. This complication can result in hemolysis and lead to anemia or heart failure because of left ventricular overload over years. Consequently, a simple and fast surgical technique potentially reducing the risk of PVL after rapid deployment aortic valve replacement can easily expand the indication for the use of this smart valve to real bicuspidy and regurgitant aortic valves.

Following this assumption, we have developed a technique that can be used to stabilize the aortic annulus and minimize the risk of PVL after implantation.

PATIENTS AND SURGICAL TECHNIQUE

To test the technique, six patients with severe symptomatic aortic valve stenosis underwent aortic valve replacement with the new technique at our center. One patient also carried aortic regurgitation grade 2. All patients signed informed consents.

Rapid deployment aortic valve replacement was performed through a full sternotomy (n = 4) or an upper hemisternotomy (n = 2), with the use of INTUITY Valve System, Model 8300A (Edwards Lifesciences, Inc). The INTUITY is a stented, trileaflet, bovine pericardial bioprosthesis (available in sizes 19, 21, 23, 25, and 27 mm) with a cloth-covered balloon-expandable frame attached to the inflow aspect of the valve. The nominal balloon inflation pressure needed to expand the frame within the left ventricular outflow tract and secure the valve ranged between 4.5 and 5.0 atm. Layers of low-density polyester cloth enveloped the frame to promote a relatively blood-tight seal. The frame length extending below the annulus ranged between 6.6 and 8.0 mm.

After initiation of cardiopulmonary bypass, aortic cross-clamping, and cardioplegic arrest, a standard aortotomy is performed. Native leaflets are excised, and the annulus is debrided as usual. As shown in Figure 1B (test in an animal model), a 3-0 polypropylene purse string suture is performed along the aortic annulus after the leaflet removal. The suture starts at the left side (surgical view) of the commissure between the noncoronary cusp and the left coronary cusp and continues clockwise just below the aortic annulus and behind the commissures (Fig. 2). Care is required when the suture approaches the fibrous trigon to prevent atrioventricular blocks. At the end of this phase, the purse string suture is not pulled and remains in stand-by.

Then, three guiding sutures are placed, centered at the nadir of the each aortic cusp, to facilitate seating of the valve

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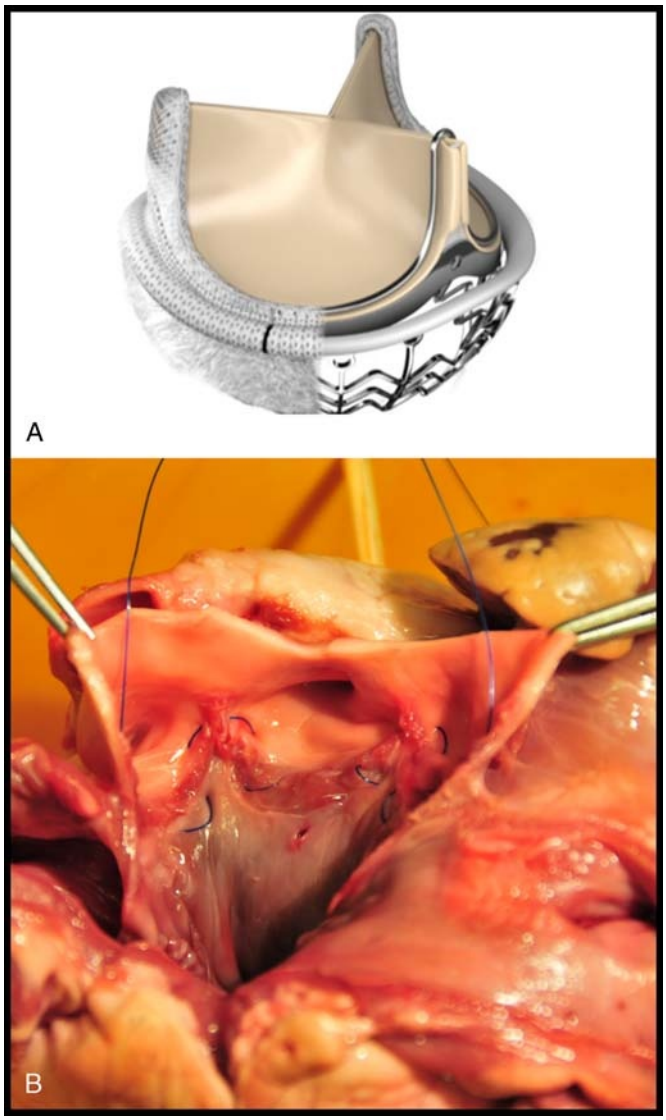

FIGURE 1. A, The rapid deployment INTUITY aortic valve (Edwards Lifesciences, Inc). B, In an explanted pig heart, we performed the purse string suture all around the aortic annulus with a 3-0 polypropylene suture.

within the surgical annulus. Once the valve is properly positioned, the snares are cinched. A balloon catheter is inserted through the delivery system and inflated. The pressure required for optimal frame expansion varies by valve size and range between 3 and 5 atm. After full expansion, the delivery system and valve holder are simultaneously withdrawn. The snares are removed, and the sutures are tied. Finally, the purse string suture is pulled and tied to adapt and narrow the aortic annulus around the bioprosthesis to prevent all kinds of postoperative PVL. Aortotomy is repaired in customary fashion.

RESULTS

The technique was tested, at first in explanted pig hearts in the animal laboratory to test the potential risk of conduction system damage and then in six standard patients experiencing aortic valve stenosis to investigate its safety and feasibility. Mean (SD) age was 79 (6.2) years (2 women, 4 men), mean (SD) left ventricle ejection fraction was 51% (8.4%), the mean (SD) preoperative aortic orifice area was 0.8 (0.2) cm^2 [indexed, 0.4 (0.1) cm^2], and the mean (SD) gradient was 40 (14) mm Hg. In this short preliminary experience, the mean time to perform the annulus stabilization technique as described earlier was 2.6 minutes, and it was performed using a 3-0 polypropylene suture. The mean (SD) aortic cross-clamp time was 43 (14) minutes, the mean (SD) cardiopulmonary bypass time was 60 (13) minutes, and the mean (SD) surgical time was 139 (27) minutes. The implanted valves were 21 mm (1), 23 mm (3), 25 mm (1) and 27 mm (1), and the mean (SD) implanting time was 9.5 (1.2) minutes. All patients survived surgery and were discharged from the hospital [mean intensive care unit stay, 1.8 (0.8) days; mean hospital stay, 12 (5) days]. There were no new intracardiac conduction system disturbances reported, and a permanent pacemaker implantation was not required in any of the patients. The intraoperative and the postoperative echocardiogram confirmed successful positioning of the valve, and no PVL was observed. Nevertheless, this is a very small cohort of patients, and it is unlikely that a study this small could detect a perivalvular leak even without the annular technique.

The predischarge transaortic peak and mean gradients were 18 (4) and 9.4 (1.8) mm Hg, respectively, with mean left ventricle ejection fraction of 52% (12%).

DISCUSSION

The INTUITY and the new INTUITY Elite Valve Systems are rapid deployment aortic bioprosthesis allowing a fast and easy aortic valve replacement when compared with the standard bioprosthesis.[1–4]

Nevertheless, the indication in case of true aortic valve bicuspidy and pure aortic valve insufficiency is still controversial

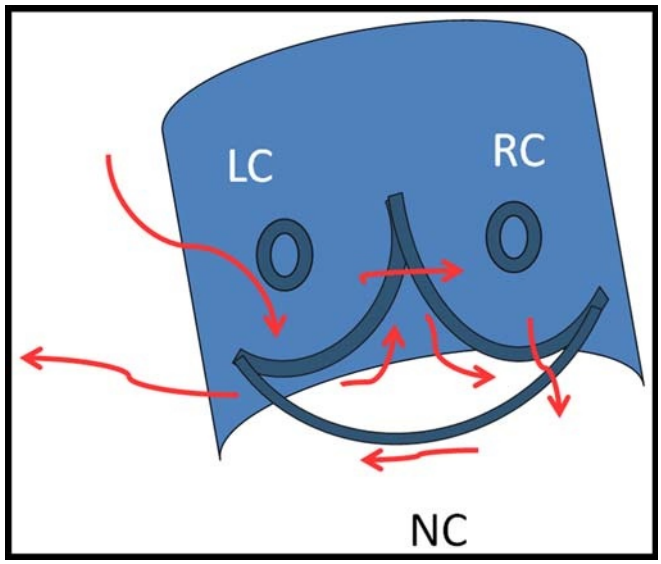

FIGURE 2. A schematic view of the 3-0 polypropylene purse string suture (red arrows), seen from the surgeon's point of view. LC, left coronary cusp; NC, noncoronary cusp; RC, right coronary cusp.

because of the risk of postoperative grade 2, 3, or 4 PVL. The PVL represents a rare complication related to this valve and is probably attributable to the annulus-valve size mismatch and to the characteristics of the annulus itself (more flexible and more mobile in regurgitant aortic valves than in calcified stenosed valves).

In two preliminary trials, the TRITON and the FOUNDATION studies, the mean rate of moderate and severe postoperative PVLs after implantation in pure stenosed aortic valves ranges between 1.2% and 1.6%, and some patients required reoperation. Therefore, this complication should be addressed to guarantee optimal clinical results. The design of the new Elite valve seems better adapted to the aortic annulus, and the tools for the valve sizing are the same used for the Edwards Perimount Magna Ease (therefore, more familiar for surgeons).

Another help for preventing the PVL, in particular in bicuspidy and insufficient aortic valves, can be the use of the described annulus stabilization technique.

During our preliminary experience in standard patients with aortic stenosis, the technique was easily performed through both full sternotomies and upper ministernotomies, the time used to prepare the purse string suture ranged between 2 and 3 minutes, and it was safe for the conduction system (the technique was tested, at first, in an animal laboratory with explanted pig hearts to identify potential risks for the conduction system).

In conclusion, in this preliminary experience (only six patients), rapid deployment aortic valve replacement through a full sternotomy or an upper hemisternotomy approach with the use of aortic annulus stabilization technique was safe, and no PVL was observed (not even traces). However, future studies on large series of patients are necessary to confirm the safety and effectiveness of this technique in preventing PVL in patients with true bicuspid aortic valves or pure aortic regurgitation.

LIMITATION OF THE STUDY

The present study represents a preliminary report on a new technique for preventing postoperative PVL after rapid deployment aortic valve implantation. Further clinical reports with more patients enrolled are mandatory to confirm efficacy and utility of this technique.

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